

Serial No. 10/027,401  
Docket No. 0081.01**REMARKS****I. Introductory Comments**

In the Office Action under reply, the Examiner objected to claim 42 in view of its misnumbering, indicated that the election requirement has been withdrawn, made a statement concerning compliance with the conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §119(e), and rejected the claims as follows: under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-6 and 8 of U.S. Patent No. 6,294,204 (claims 1-15, 18-21, 24 and 29-42); under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-6 and 8 of U.S. Patent No. 6,294,204 in view of Tomlinson *et al.* (U.S. Patent No. 6,211,250) (claims 16, 17, 22, 23, 25 and 26); under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-6 and 8 of U.S. Patent No. 6,294,204 in view of Gordon *et al.* (U.S. Patent No. 6,001,336) (claims 27 and 28); under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-4, 7 and 11-14 of U.S. Patent No. 6,572,894 (claims 1-15, 18-21, 24 and 29-42); under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-4, 7 and 11-14 of U.S. Patent No. 6,572,894 in view of Tomlinson *et al.* (U.S. Patent No. 6,211,250) (claims 16, 17, 22, 23, 25 and 26); and under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-4, 7 and 11-14 of U.S. Patent No. 6,572,894 in view of Gordon *et al.* (U.S. Patent No. 6,001,336). The rejections are traversed for reasons provided below.

**II. Amendments to the Specification and Claims**

The specification has been amended to update the cross reference to related applications. Support for the reciting the related applications is provided in the Application Data Sheet included in the December 21, 2001, application filing and reflected on the filing receipt.

Claims 1-42 were previously pending in the application. Claims 1, 4, 8, 30 and 40-42 have been amended. Claim 7 has been deleted without prejudice. No claims have been added. Consequently, claims 1-6 and 8-42 remain pending.

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Support for the amendments is identified below. Additional support other than that identified below may exist in the specification for one or more amendments to the claims.

Claim 1 has been amended to include the element recited in claim 7. As claim 7 represents an originally filed claim, the requisite support for element is satisfied.

Misnumbered claim 41 (i.e., the "second" claim 41) has been amended to correctly read as claim --42--.

Claims 4, 8, 30 and 40-42 have been amended to delete the dash ("—") with the word -- to --. Applicant notes that this change improves clarity, particular with respect to the negative value recited in claim 40. In addition, referenced claim numbers in claim 42 have been written out to improve clarity. Inasmuch as these changes merely improve clarity of the claims, no new matter is added by these corrections.

As support for the claimed subject matter is found in the application as filed, no new matter is introduced by the entry of the above-identified changes to the claims. The changes to the claims are made for clarification purposes only should not be interpreted as acquiescence in any claim rejection.

### **III. The Examiner's Claim Objection**

The Examiner objected to claim 42 because the claims was misnumbered. In response, Applicant has corrected the misnumbering. Reconsideration and removal of the objection is respectfully requested.

### **IV. The Election Requirement**

On page 2 of the Office Action, the Examiner indicated that the election requirement has been withdrawn. Applicant acknowledges this action.

### **V. The Priority Claim**

The Examiner alleged that the Applicant did not comply with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §119(e). Although Applicant asserts that all conditions have been met (e.g., the specific reference to prior applications was provided in an Application Data Sheet), Applicant nonetheless has amended the specification to

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include a sentence specifically referring to the prior applications to which the current application claims priority.

In view of thereof, the Examiner's concern has been addressed. If further action in this regard, the Examiner is asked to inform the undersigned.

#### VI. The First Obviousness-type Double Patenting Rejection

Claims 1-15, 18-21, 24 and 29-42 stand rejected under the judicially created doctrine of obviousness-type double patenting as being allegedly unpatentable over claims 1-6 and 8 of U.S. Patent No. 6,294,204 (hereinafter referred to as "the '204 patent"). As stated in the Manual of Patent Examining Procedure (M.P.E.P.),

[o]bviousness-type double patenting requires rejection of an application claim when the claimed subject matter is **not patentably distinct** from the subject matter claimed in a commonly owned patent when the issuance of a second patent would provide unjustified extension of the term of the right to exclude granted by a patent. See *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 58 USPQ2d 1865 (Fed. Cir. 2001); *Ex parte Davis*, 56 USPQ2d 1434, 1435-36 (Bd. Pat. App. & Inter. 2000).

See M.P.E.P. Section 804, Paragraph 8.32. (Emphasis in original). Moreover, this section of the M.P.E.P. sets forth that

[a] double patenting rejection of the obviousness-type is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103 except that the patent principally underlying the double patenting rejection is not considered prior art. *In re Braithwaite*, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

*Id.* As a consequence,

[T]he factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are employed when making an obvious-type double patenting analysis. These factual inquiries are summarized as follows:

(A) Determine the scope and content of a patent claim and the prior art relative to a claim in the application at issue;

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(B) Determine the differences between the scope and content of the patent claim and the prior art as determined in (A) and the claim in the application at issue;

(C) Determine the level of ordinary skill in the pertinent art; and

(D) Evaluate any objective indicia of nonobviousness.

*Id.*

Having set forth the standard for determining the propriety of a rejection under the judicially created doctrine of obviousness-type double patenting, it is now necessary to apply that standard to the present case.

#### A. Steps A and B

With regard to determining the scope and content of the prior art relative to a claim in the application at issue -- a component of Step A -- and determining the differences between the scope and content of the prior art and the claim in the application at issue -- a component of Step B --, Applicant urges that the prior art-related portion of the obvious-type double patenting analysis has already been performed. Specifically, the Examiner has ostensibly found the pending claims patentably distinct over the prior art since the only rejections presented in the Office Action are double patenting rejections. As the prior art-related portion of the analysis is complete, the remaining analysis provided herein centers on the patentably distinct differences of the present claims over claims 1-6 and 8 of the '204 patent.

The obviousness-type double patenting analysis now turns to a comparison between the scope and content of claims 1-6 and 8 of the '204 patent (as required in Step A) to the claims in the application at issue (as required in Step B). This comparison is most readily made by comparing the scope and content of independent claim (i.e., claim 1) contained within claims 1-6 and 8 of the '204 patent and the scope and content of claim 1, the only independent claim, of the present application.

For convenience, a comparison of the two claims is provided in tabular form in Table 1. This comparison represents "Step A" in the obvious-type double patenting analysis.

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Table 1  
Step A: Comparison of Claim 1 of the Present Application and  
Claim 1 of the '204 Patent.

Independent Claim of Present Application	Independent Claims of '204 Patent
1. A process for the production of polymeric microparticles comprising	1. A process for the production of morphologically uniform microcapsules consisting of
dissolving a polymer in a halogen-free solvent that is at least partially water-miscible to form a polymer solution	forming a polymer solution by dissolving a polymer selected from the group consisting of polyamides, polyanhydrides, polyorthoesters, polyacetates, polylactones, polyorthocarbonates, and polyesters in a water-miscible halogen-free solvent or partially water-miscible halogen-free solvent
adding a non-water soluble active agent to the polymer solution to form a drug phase contained in a vessel	adding a solution of a water-soluble active agent to the polymer solution to form a polymer/active agent dispersion
adding a predetermined amount of an aqueous surfactant phase to the vessel containing the drug phase with mixing, said predetermined amount being sufficient to (i) result in a volume fraction of the surfactant phase of at least 0.60, and (ii) provide that the surfactant phase becomes the continuous phase and extraction medium in order to extract an amount of said solvent from said drug phase such that a suspension of microparticles is produced upon addition of the surfactant phase to the drug phase without requiring removal of the solvent from the vessel.	adding an aqueous solution containing a surfactant to the polymer/active agent dispersion thereby providing a final total volume wherein the polymer/active agent dispersion is present in the total volume in an amount less than 50% v/v, and the surfactant solution is present in the total volume in an amount less than 60% v/v;
-	removing the solvent to produce microcapsules having a concentration of drug of less than 30% w/w.

Now that each claim has been described, Step B of the analysis requires a determination of the differences between the scope and content of claim 1 in the pending application and the scope and content of claim 1 in the '204 patent.

In looking at the claimed processes, differences exist between the process encompassed by the pending claims and the process encompassed by the '204 patent claims. For example, the process encompassed by the pending claims requires one less step than the process encompassed by the '204 patent claims. Specifically, the process encompassed by the claims in the pending application results in microparticles "produced upon addition of the surfactant phase" whereas the process encompassed by the '204 patent requires the removal of the solvent.

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In addition, the claims as amended encompass the step of adding the surfactant phase such that the addition will "result in a volume fraction of the surfactant phase of at least 0.60." In contrast, the process encompassed by the '204 patent requires the surfactant solution be present in the total volume in an amount less than 60%.

The Examiner states that the element of "a volume fraction of the surfactant phase of at least 0.60" (originally recited in claim 7) shares the same endpoint recited in the patented claim. Applicant respectfully disagrees. Specifically, an endpoint of "*at least 60%*" (i.e., at least 0.60) is different from the endpoint of "*less than 60%*." There simply is no overlap of values in these two ranges.

Finally, the process of the pending claims relates to hydrophobic active agents while the patented process relates to water-soluble active agents.

Consequently, there are a number of differences between these two claimed inventions.

#### B. Step C

Now that Steps A and B have been completed, the next step (i.e., Step C) requires determining the level of ordinary skill in the pertinent art. Here, the pertinent art is the field of producing microparticles containing a non-water soluble biologically active agent. See the section entitled "Field of the Invention" in the pending application. A pharmaceutical chemist having familiarity with producing microparticles containing a non-water soluble biologically active agent qualifies as one having ordinary skill.

#### C. Step D

The final step of the analysis, Step D, requires an evaluation of objective indicia of nonobviousness. Here, the pending claims possess several indicia of nonobviousness, any one of which is sufficient for patentability over the claims 1-6 and 8 of the '204 patent. For example, claims 1-6 and 8 of the '204 patent specifically require the surfactant solution is present in the total volume in an amount *less than 60%*," wherein the pending claims as amended are completely opposite by requiring an amount *greater than 60%*. In addition, the process encompassed by the '204 patent requires additional steps compared to process encompassed by the pending claims. In view of the above, there is more than enough evidence to conclude that the subject matter of claim 1 (and those dependent thereon) of the present application is nonobvious over claims 1-6 and 8 of the '204 patent.

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Moreover, the Examiner has failed to provide a satisfactory basis concerning why it would have been obvious for a pharmaceutical chemist having familiarity with producing microparticles containing a non-water soluble biologically active agent to modify the subject matter encompassed by claims 1-6 and 8 of the '204 patent in order to arrive at the claimed invention. There is no basis whatsoever for switching the "water-soluble active agent" as recited in the patented claims to the "non-water soluble active agent" recited in the pending claims. Moreover, there is no teaching or suggestion to ignore the patented claim's requirement to use a surfactant solution **less than 60%** for an amount that is **greater than 60%**. In addition, even if there were some hint or suggestion to switch to non-water soluble active agents and to use an amount of surfactant phase that is greater than 60%, there is no basis for teaching a process that requires **fewer steps**.

In view the above, Applicant respectfully requests reconsideration and removal of the nonstatutory double patenting rejection over claims 1-6 and 8 of the '204 patent. Applicant notes that reliance on the comparison of independent claim for the obvious-type double patenting analysis is for expediency purposes only. Consequently, Applicant reserves the right to argue the patentability of each and every dependent claim should the subject matter of the pending independent claim be alleged to be not patentable over claims 1-6 and 8 of the '204 patent following consideration of the arguments provided herein.

#### VII. The Second Obviousness-type Double Patenting Rejection

The Examiner has rejected claims 16, 17, 22, 23, 25 and 26 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-6 and 8 of U.S. Patent No. 6,294,204 in view of Tomlinson *et al.* (U.S. Patent No. 6,211,250).

The Examiner's position with regard to the teachings of U.S. Patent No. 6,294,204 has been discussed in Section (VI), above, although the Examiner does acknowledge that the '204 patent is silent with respect to producing compositions comprising microspheres and microsponges. With respect to Tomlinson *et al.*, this reference is cited by the Examiner as allegedly teaching that microparticles, microspheres and microsponges are considered equivalent in the art.

This rejection is respectfully traversed in view of the following remarks.

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Applicant relies on the arguments provided in Section (VI), above in support of the patentability of claims 1-15, 18-21, 24 and 29-42 over claims 1-6 and 8 of U.S. Patent No. 6,294,204. As Applicant has shown the patentability of the independent claim (as well as dependent claims 2-15, 18-21, 24 and 29-42) over claims 1-6 and 8 of U.S. Patent No. 6,294,204 and Tomlinson *et al.* is only cited with respect to claims 16, 17, 22, 23, 25 and 26, it follows that Tomlinson *et al.* does not remedy the deficiencies of the first obviousness-type double patenting rejection related to the independent claim. As a result, the independent claim (as well as the claims depending therefrom) remains patentable over claims 1-6 and 8 of U.S. Patent No. 6,294,204 in view of Tomlinson *et al.*

Applicant reserves the right to argue the patentability of each and every dependent claim should the subject matter of the pending independent claim be alleged to be not patentable over claims 1-6 and 8 of the '204 patent in view of Tomlinson *et al.* following consideration of the arguments provided herein.

#### VIII. The Third Obviousness-type Double Patenting Rejection

The Examiner has rejected claims 27 and 28 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-6 and 8 of U.S. Patent No. 6,294,204 in view of Gordon *et al.* (U.S. Patent No. 6,001,336).

The Examiner's position with regard to the teachings of U.S. Patent No. 6,294,204 has been discussed in Section (VI), above, although the Examiner does acknowledge that the '204 patent discusses a "suspension" while the pending claim discusses a "solution." With respect to Gordon *et al.*, this reference is cited by the Examiner as allegedly teaching that a solution is formed when a hydrophilic component is mixed in water, whereas a hydrophobic component is suspended in the solution to form a suspension.

This rejection is respectfully traversed in view of the following remarks.

Applicant relies on the arguments provided in Section (VI), above in support of the patentability of claims 27 and 28 over claims 1-6 and 8 of U.S. Patent No. 6,294,204. As Applicant has shown the patentability of the independent claim (as well as dependent claims 2-15, 18-21, 24 and 29-42) over claims 1-6 and 8 of U.S. Patent No. 6,294,204 and Gordon *et al.* is only cited with respect to claims 27 and 28, it follows that Gordon *et al.* does not remedy the deficiencies of the first obviousness-type double patenting rejection with respect to the



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independent claim. As a result, the independent claim (as well as the claims depending therefrom) remains patentable over claims 1-6 and 8 of U.S. Patent No. 6,294,204 in view of Gordon *et al.*

Applicant reserves the right to argue the patentability of each and every dependent claim should the subject matter of the pending independent claim be alleged to be not patentable over claims 1-6 and 8 of the '204 patent in view of Gordon *et al.* following consideration of the arguments provided herein.

#### **IX. The Fourth Obviousness-type Double Patenting Rejection**

The Examiner has rejected claims 1-15, 18-21, 24 and 29-42 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-4, 7 and 11-14 of U.S. Patent No. 6,572,894.

This rejection is respectfully traversed in view of the following remarks.

Having set forth the for step process determining the propriety of a rejection under the judicially created doctrine of obviousness-type double patenting in Section (VI), above, the application of that standard to the present case will now be discussed.

##### **A. Steps A and B**

With regard to determining the scope and content of the prior art relative to a claim in the application at issue -- a component of Step A -- and determining the differences between the scope and content of the prior art and the claim in the application at issue -- a component of Step B --, Applicant urges that the prior art-related portion of the obvious-type double patenting analysis has already been performed. Specifically, the Examiner has ostensibly found the pending claims patentably distinct over the prior art since the only rejections presented in the Office Action are double patenting rejections. As the prior art-related portion of the analysis is complete, the remaining analysis provided herein centers on the patentably distinct differences of the present claims over claims 1-4, 7 and 11-14 of the '894 patent.

The obviousness-type double patenting analysis now turns to a comparison between the scope and content of claims 1-4, 7 and 11-14 of the '894 patent (as required in Step A) to the claims in the application at issue (as required in Step B). This comparison is most readily made by comparing the scope and content of the independent claim (i.e., claim 1) contained within claims

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1-4, 7 and 11-14 of the '894 patent and the scope and content of claim 1, the only independent claim, of the present application.

For convenience, a comparison of the two claims is provided in tabular form in Table 2. This comparison represents "Step A" in the obvious-type double patenting analysis.

Table 2  
Step A: Comparison of Claim 1 of the Present Application and  
Claim 1 of the '894 Patent

Independent Claim of Present Application	Independent Claims of '204 Patent
1. A process for the production of polymeric microparticles comprising	1. A process for the production of morphologically uniform microcapsules that comprise biodegradable polymers or copolymers and contain at least one peptide, protein or other water-soluble, biologically active substance as the active ingredient, by an induced phase transition process which comprises:
dissolving a polymer in a halogen-free solvent that is at least partially water-miscible to form a polymer solution	dissolving a polymer selected from the group consisting of polyamides, polyanhydrides, polyorthoesters, polyacetates, polylactones, polyorthocarbonates, polyesters, and polyesters of hydroxycarboxylic acids or block copolymers of polyesters of hydroxycarboxylic acids and polyethylene glycol, in a halogen-free solvent that is partially water-miscible;
adding a non-water soluble active agent to the polymer solution to form a drug phase contained in a vessel	Dispersing therein a solution of the active ingredient to form a W/O emulsion;
adding a predetermined amount of an aqueous surfactant phase to the vessel containing the drug phase with mixing, said predetermined amount being sufficient to (i) result in a volume fraction of the surfactant phase of at least 0.60, and (ii) provide that the surfactant phase becomes the continuous phase and extraction medium in order to extract an amount of said solvent from said drug phase such that a suspension of microparticles is produced upon addition of the surfactant phase to the drug phase without requiring removal of the solvent from the vessel.	adding an aqueous solution that contains a surfactant or a mixture of surfactants to this W/O emulsion wherein the surfactant solution is present in an amount less than 60% v/v;
	Removing the solvent, thus forming the microcapsules; and

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Independent Claim of Present Application	Independent Claims of '204 Patent
-	Optionally, removing residual solvent, unencapsulated active ingredient and/or surfactant.

Now that each claim has been described, Step B of the analysis requires a determination of the differences between the scope and content of claim 1 in pending application and the scope and content of claim 1 in the '894 patent.

Like the previous analysis with respect to the '204 patent, the process encompassed by the pending claims requires one less step than the process encompassed by the '894 patent claims. Specifically, the process encompassed by the claims in the pending application results in microparticles "produced upon addition of the surfactant phase" whereas the process encompassed by the '894 patent requires the step of removing the solvent.

In addition, the claims as amended encompass the step of adding the surfactant phase such that the addition will "result in a volume fraction of the surfactant phase of at least 0.60." In contrast, the process encompassed by the '894 patent (like the '204 patent) requires the surfactant solution be present in the total volume in an amount less than 60%.

The Examiner states that the element of "a volume fraction of the surfactant phase of at least 0.60" (originally recited in claim 7) shares the same endpoint recited in the patented claim. Applicant respectfully disagrees. Specifically, an endpoint of "*at least 60%*" (i.e., at least 0.60) is different from the endpoint of "*less than 60%.*" There simply is no overlap of values in these two ranges.

Finally, the process of the pending claims relates to hydrophobic active agents while the patented process relates to peptide, protein or other water-soluble, biologically active substances.

Consequently, there are a number of differences between these two claimed inventions.

#### B. Step C

Now that Steps A and B have been completed, the next step (i.e., Step C) requires determining the level of ordinary skill in the pertinent art. Here, the pertinent art is the field of producing microparticles containing a non-water soluble biologically active agent. See the section entitled "Field of the Invention" in the pending application. A pharmaceutical chemist having familiarity with producing microparticles containing a non-water soluble biologically active agent qualifies as one having ordinary skill.

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### C. Step D

The final step of the analysis, Step D, requires an evaluation of objective indicia of nonobviousness. Here, the pending claims possess several indicia of nonobviousness, any one of which is sufficient for patentability over the claims 1-4, 7 and 11-14 of the '894 patent. For example, claims 1-4, 7 and 11-14 of the '894 patent specifically require the surfactant solution is present in the total volume in an amount *less than 60%*," wherein the pending claims as amended are completely opposite by requiring an amount *greater than 60%*. In addition, the process encompassed by the '894 patent requires additional steps compared to process encompassed by the pending claims. In view of the above, there is more than enough evidence to conclude that the subject matter of claim 1 (and those dependent thereon) of the present application is nonobvious over claims 1-4, 7 and 11-14 of the '894 patent.

Moreover, the Examiner has failed to provide a satisfactory basis concerning why it would have been obvious for a pharmaceutical chemist having familiarity with producing microparticles containing a non-water soluble biologically active agent to modify the subject matter encompassed by claims 1-4, 4 and 11-14 of the '894 patent in order to arrive at the claimed invention. There is no basis whatsoever for switching the "peptide, protein or other water-soluble, biologically active substances" as recited in the patented claims to the "non-water soluble active agent" recited in the pending claims. Moreover, there is no teaching or suggestion to ignore the patented claim's requirement to use a surfactant solution *less than 60%* for an amount that is *greater than 60%*. In addition, even if there were some hint or suggestion to switch to non-water soluble active agents and use an amount of surfactant phase that is greater than 60%, there is no basis for teaching a process that requires fewer steps.

In view of all the above, Applicant respectfully requests reconsideration and removal of the nonstatutory double patenting rejection over claims 1-4, 7 and 11-14 of the '894 patent. Applicant notes that reliance on the comparison of independent claims for the obvious-type double patenting analysis is for expediency purposes only. Consequently, Applicant reserves the right to argue the patentability of each and every dependent claim should the subject matter of the pending independent claim be alleged to be not patentable over claims 1-4, 7 and 11-14 of the '894 patent following consideration of the arguments provided herein.

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**X. The Fifth Obviousness-type Double Patenting Rejection**

The Examiner has rejected claims 16, 17, 22, 23, 25 and 26 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-4, 7 and 11-14 of U.S. Patent No. 6,572,894 in view of Tomlinson *et al.* (U.S. Patent No. 6,211,250).

The Examiner's position with regard to the teachings of U.S. Patent No. 6,572,894 has been discussed in Section (IX), above, although the Examiner does acknowledge that the '894 patent is silent with respect to producing compositions comprising microspheres and microsponges. With respect to Tomlinson *et al.*, this reference is cited by the Examiner as allegedly teaching that microparticles, microspheres and microsponges are considered equivalent in the art.

This rejection is respectfully traversed in view of the following remarks.

Applicant relies on the arguments provided in Section (IX), above in support of the patentability of claims 1-15, 18-21, 24 and 29-42 over claims 1-4, 7 and 11-14 of U.S. Patent No. 6,572,894. As Applicant has shown the patentability of the independent claim (as well as dependent claims 2-15, 18-21, 24 and 29-42) over claims 1-4, 7 and 11-14 of U.S. Patent No. 6,572,894 and Tomlinson *et al.* is only cited with respect to claims 16, 17, 22, 23, 25 and 26, it follows that Tomlinson *et al.* does not remedy the deficiencies of the first obviousness-type double patenting rejection related to the independent claim. As a result, the independent claim (as well as the claims depending therefrom) remains patentable over claims 1-4, 7 and 11-14 of U.S. Patent No. 6,572,894 in view of Tomlinson *et al.*

Applicant reserves the right to argue the patentability of each and every dependent claim should the subject matter of the pending independent claim be alleged to be not patentable over claims 1-4, 7 and 11-14 of the '894 patent in view of Tomlinson *et al.* following consideration of the arguments provided herein.

**XI. The Sixth Obviousness-type Double Patenting Rejection**

The Examiner has rejected claims 27 and 28 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-4, 7 and 11-14 of U.S. Patent No. 6,572,894 in view of Gordon *et al.* (U.S. Patent No. 6,001,336).

The Examiner's position with regard to the teachings of U.S. Patent No. 6,572,894 has been discussed in Section (IX), above, although the Examiner does acknowledge that the '894

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patent discusses a "suspension" while the pending claim discusses a "solution." With respect to Gordon *et al.*, this reference is cited by the Examiner as allegedly teaching that a solution is formed when a hydrophilic component is mixed in water, whereas a hydrophobic component is suspended in the solution to form a suspension.

This rejection is respectfully traversed in view of the following remarks.

Applicant relies on the arguments provided in Section (IX), above in support of the patentability of claims 27 and 28 over claims 1-4, 7 and 11-14 of U.S. Patent No. 6,572,894. As Applicant has shown the patentability of the independent claim (as well as dependent claims 2-15, 18-21, 24 and 29-42) over claims 1-4, 7 and 11-14 of U.S. Patent No. 6,572,894 and Gordon *et al.* is only cited with respect to claims 27 and 28, it follows that Gordon *et al.* does not remedy the deficiencies of the first obviousness-type double patenting rejection relating the independent claim. As a result, the independent claim (as well as the claims depending therefrom) remains patentable over claims 1-4, 7 and 11-14 of U.S. Patent No. 6,572,894 in view of Gordon *et al.*

Applicant reserves the right to argue the patentability of each and every dependent claim should the subject matter of the pending independent claim be alleged to be not patentable over claims 1-4, 7 and 11-14 of the '894 patent in view of Gordon *et al.* following consideration of the arguments provided herein.

#### VIII. Conclusion

In view of the foregoing, Applicants submit that the pending claims satisfy the requirements of patentability and are therefore in condition for allowance. Reconsideration and withdrawal of all objections and rejections is respectfully requested and a prompt mailing of a Notice of Allowance is earnestly solicited.

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If a telephone conference would expedite the prosecution of the subject application, the Examiner is requested to call the undersigned at (650) 620-5506.

Respectfully submitted,  
Nektar Therapeutics

Date: June 30, 2004

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